MAR 1 5 2002

K013867

SECTION 16: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

16.1 SUBMITTER INFORMATION

a. Company Name:	FRIADENT GmbH.
b. Company Address:	Steinzeugstrasse 50 Mannheim D-68229 Germany
c. Company Phone: Company Facsimile:	(011) 49 621 4302 1121 (011) 49 621 4302 2121
d. Contact Person:	Heike Dietzler Regulatory Affairs Manager
e. Date Summary Prepared:	February 21, 2002

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	XiVE® Dental Implant System
b. Classification Name:	Endosseous Dental Implants 21 CFR 872.3640

16.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Nobel BioCare	Branemark System Standard 3.75mm Fixture	K925765	10/05/93
FRIADENT GmbH	FRIALIT-2 Dental Implant With Deep Profile Surface	K945847	03/15/95

16.4 DEVICE DESCRIPTION

The XiVE Dental Implant System consists of subgingival threaded dental implants in 3.4 - 5.5mm diameters with 8 – 18mm lengths. The implants are coated with the FRIOS Deep Profile Surface. The XiVE Dental Implant System is comprised of dental implants, surgical and laboratory instruments and prosthetic components. The system is designed for two stage procedures for single tooth replacement and the fixation of bridges and complete dentures.

16.5 SUBSTANTIAL EQUIVALENCE

The XiVE® dental implant is substantially equivalent to the current FRIALIT-2® Dental Implant Systems in terms of design, materials, coatings, prosthetic options and intended use. The XiVE® dental implant is substantially equivalent to the Nobel BioCare Branemark 3.75mm dental implant in terms materials, functionality, mechanical strength and intended use.

16.6 INTENDED USE

Once the XiVE Dental Implant has osseointegrated, it serves to support single tooth, bridge and overdenture restorations.

16.7 TECHNOLOGICAL CHARACTERISTICS

The XiVE® dental implant is identical to the current FRIALIT-2® dental implants in terms of coatings, materials and prosthetic options. The XiVE® dental implant is available in 3.4, 3.8, 4.5 and 5.5 mm screw-type implants with FRIOS® Deep Profile Surface. The lengths of the implants range from 8 – 18mm. The XiVE dental implants are constructed of CP-2 titanium. A variety of prosthetic options are available for the XiVE system including, MH-6, MH-2, EstheticBase, Cerabase, AuroBase and Protect Abutments, PassivFit, Ball and Socket Attachments, Bar Copings, Round Bar, Bar Clip, and Telescopic

Abutments. The XiVE dental implant system was tested for compressive and static strength and finite element analysis.

The XiVE Dental Implant system is equivalent to the Nobel BioCare Branemark Standard Dental Implant System in terms of design, mechanical strength and intended use.

16.8 CLASS III CERTIFICATION AND SUMMARY

This notification contains a Class III certification and summary of adverse safety and effectiveness information pursuant to 513(f) of the Federal Food, Drug, and Cosmetic Act.

16.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission. Performance evaluations of the XiVE dental implant system show that the device performs as intended. Comparison the XiVE dental implant system to the predicate devices, show that the device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

C/O Ms. Carol Patterson
President
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K013867
Trade/Device Name: Xive Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: February 21, 2002
Received: February 22, 2002

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013867

INDICATION FOR USE

510(k) Number: K013867

Device Name: XiVE® Dental Implant System

Indications for Use: The XiVE Dental Implant System is indicated as follows:

Once the implant has osseointegrated, it serves to support single tooth, bridge and overdenture restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013867